For the ordinary person in the extraordinary moment

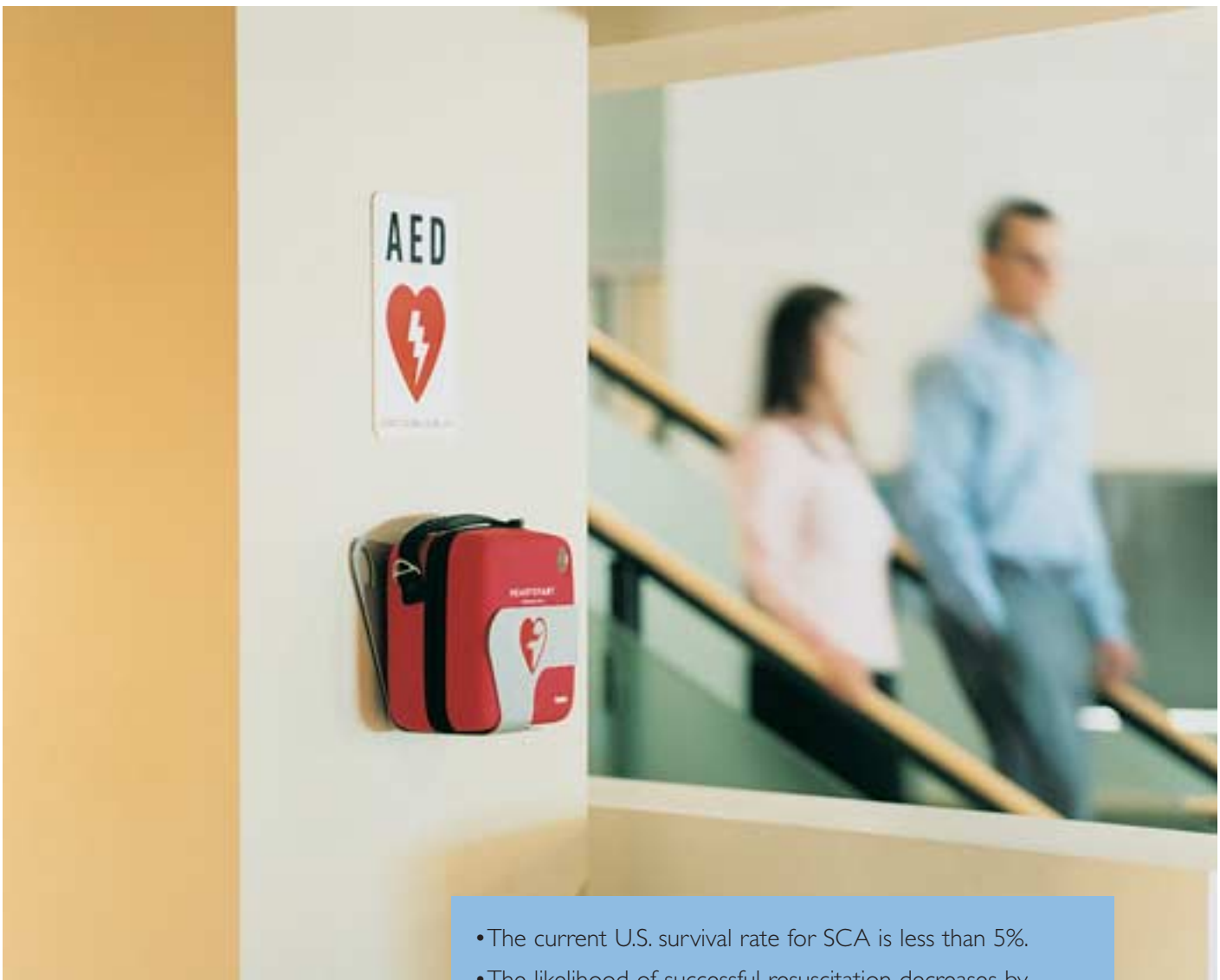
Philips HeartStart OnSite Defibrillator

Product information

Updated for Guidelines 2005

PHILIPS

Sudden cardiac
anyone, anytime,



- The current U.S. survival rate for SCA is less than 5%.
- The likelihood of successful resuscitation decreases by about 10% with every minute that passes.
- An additional 40,000 lives could be saved each year in the U.S. alone with widespread access to defibrillators.

arrest can happen to anywhere.

Power to save a life

Each year sudden cardiac arrest (SCA) strikes approximately 340,000 people in the U.S. alone, and hundreds of thousands more worldwide. The majority of these people have no warning, since they show no prior symptoms. And sadly, fewer than 5% survive, often because emergency medical services cannot reach them in time.

SCA most often occurs when the electrical system of the heart becomes chaotic, causing it to stop beating effectively. Lacking proper blood flow, the person becomes unresponsive, stops breathing, and will die unless promptly treated. CPR is important, but it alone cannot restore a normal heart rhythm. A "shock" from a defibrillator is the most effective way to restore the heart's normal pumping rhythm. The victim's best chance of survival is to receive that shock within 5 minutes of collapse. Just as seat belts or airbags do not save every life in a traffic accident, a defibrillator will not save every person who suffers a sudden cardiac arrest. Yet many lives could be saved if more people could be reached more quickly.

Philips HeartStart Defibrillators enable virtually anyone to treat the most common cause of SCA by delivering a shock quickly and effectively, wherever it happens – at work, at play, in the air – providing the power to save a life.

The Philips HeartStart

OnSite Defibrillator

Philips, the leader in portable defibrillation technology, designed the HeartStart OnSite Defibrillator for the ordinary person in the extraordinary moment. The first commercial defibrillator available without a prescription, the OnSite is designed to be the easiest to use and most reliable defibrillator available.[1,2] Our innovative technology, based on extensive research and user feedback, has produced a defibrillator so easy to use that you can potentially save the life of a coworker, friend, or anyone else stricken with sudden cardiac arrest.

Weighing just 3.3 lbs., this small and lightweight defibrillator can be easily carried to the victim's side. Using clear, calm voice instructions, the OnSite Defibrillator guides you through each step of defibrillation, including CPR Coaching. Integrated SMART Pads placed on the victim's bare skin transmit information to the defibrillator, which senses and adapts to your actions every step of the way.

HeartStart OnSite includes proven Philips technologies for heart rhythm assessment (SMART Analysis) and defibrillation energy delivery (SMART Biphasic). And like all HeartStart Defibrillators, it can be used to treat infants and children as well as adults.[3]

The first defibrillator available without a prescription to commercial users

Ready when needed

The OnSite has a long-life battery:

- 5-year shelf life plus 4-year installed life.
- The same battery technology used with confidence in millions of cameras.

Automatic self-tests help ensure continued readiness:

- Daily self-tests check electrical components, subsystems and battery.
- A self-test also verifies that the pads cartridge is installed and in working order.
- A blinking green "Ready" light means the OnSite has passed its last self-test, so you can be confident the defibrillator is ready for use.

Easy to use

Using the HeartStart OnSite Defibrillator is simple. Pulling the green handle activates the defibrillator and voice instructions. These instructions are paced to your actions, to help guide you through the entire process – from placing each pad on the patient to delivering a defibrillation shock.

HeartStart OnSite determines if a heart rhythm is shockable.

- If a shock is indicated, the defibrillator directs you to press the flashing orange Shock button. Then HeartStart OnSite delivers a dose of low-energy biphasic therapy, a highly-effective defibrillation waveform that is also gentle to the heart.
- If a shock is not indicated, the OnSite Defibrillator instructs you to perform CPR. While performing CPR, the defibrillator's voice instructions can be activated to coach you on the frequency and depth of compressions as well as breaths. HeartStart OnSite also reminds you to call emergency medical services (EMS). And should EMS need a summary of care, it can be retrieved from the defibrillator's internal memory. An EMS provider simply presses the i-button and HeartStart OnSite verbally recounts events from its last clinical use.

Replaceable SMART Pads Cartridges

The cartridge contains two adhesive pads that are placed on the patient's bare skin as indicated by the pictures on the pads. The pads are "smart" because they sense when they have been removed from the cartridge and when each has been applied to the patient, adjusting the voice instructions to your actions.

The HeartStart OnSite can be used on patients of any age, including infants and children. OnSite senses when the special infant/child SMART Pads Cartridge is installed. It automatically adjusts to use a lower energy level more appropriate for infants and children, and also provides coaching for performing infant/child CPR.

To practice your skills, a special training pads cartridge (adult or infant/child) can be installed in the defibrillator. It suspends the defibrillator's ability to shock, while walking you through patient care scenarios.

Designed to help save a life in extraordinary circumstances

Lightweight
Just 3.3 pounds fully equipped.

Intuitive
Clean design and clear voice instructions, including CPR Coaching, instill the confidence that's needed when treating a person in cardiac arrest.

Effective
Patented SMART Analysis heart rhythm assessment and SMART Biphasic defibrillation therapy, clinically proven in nearly 10 years of use. No other external defibrillation therapy has been supported by more published clinical data.[9]

And with patented Quick Shock, the OnSite is fastest in class at delivering a shock after CPR. Studies show that minimizing time to shock after CPR may improve survival.[4,5,6,7,8] As American Heart Association Guidelines 2005 notes, "Reduction in the interval from compression to shock delivery by even a few seconds can increase the probability of shock success."[10]

Product specifications

Defibrillator

Defibrillator Model	HeartStart M5066A
Defibrillator Family	HS1
How Supplied	Defibrillator, Owner's Manual, battery, 1 adult SMART Pads cartridge, Quick Reference Guide and Quick Start poster
Waveform	Truncated Exponential Biphasic. Waveform parameters adjusted as a function of each patient's impedance.
Energy	Single energy output. Adult: nominal 150 Joules into a 50 ohm load. Infant/Child: nominal 50 Joules into a 50 ohm load. Automatically set based on type of SMART Pads cartridge installed.
Shock-to-Shock Cycle Time	Typically less than 20 seconds between shocks in a series.
Quick Shock	Able to deliver a shock after the end of a CPR interval, typically in eight seconds.
Voice Instructions	Detailed voice messages guide responder through use of the defibrillator.
CPR Coaching	Instructions for adult and infant/child CPR available at user's option.
Shock Delivery	Via adhesive pads placed on patient's bare skin as illustrated on pads.
Controls	Green SMART Pads cartridge handle, green On/Off button, blue i-button, orange Shock button
Indicators	Ready light; blue i-button; caution light

Physical Specifications

Size	2.8 x 7.4 x 8.3 inches (7 x 19 x 21 cm) H x D x W
Weight	With battery and pads case: 3.3 lbs. (1.5 kg) Without battery or pads case: 2.4 lbs. (1 kg)

Environmental/Physical Requirements

Sealing	Solid objects per EN60529 class IP2X Drip-proof per EN60529 class IPX1
Temperature	Operating: 32° - 122° F (0°- 50° C) Standby: 50° - 109° F (10°- 43° C)
Humidity	Operating: 0% to 95% relative, non-condensing Standby: 0% to 75% relative, non-condensing
Altitude	Operating: 0 to 15,000 feet Standby: 0 to 8,500 feet > 48 hours and 8,500 to 15,000 feet < 48 hours
Shock/Drop Abuse	Withstands 1 meter drop to any edge, corner or surface.
Vibration	Meets EN1789 random and swept sine, road ambulance specification in operating and standby states.
EMI (Radiated/Immunity)	Meets EN55011 Group 1 Level B Class B and EN61000-4-3.

Patient Analysis System

Patient Analysis	Evaluates patient ECG to determine if a rhythm is shockable. Rhythms considered shockable are ventricular fibrillation (VF) and certain ventricular tachycardias (VT) associated with lack of circulation. For safety reasons, some VT rhythms associated with circulation will not be interpreted as shockable, and some very low-amplitude or low-frequency rhythms will not be interpreted as shockable VF.
Sensitivity/Specificity	Meets AAMI DF80 guidelines and AHA recommendations for adult defibrillation (Circulation 1997;95:1677-1682).
Artifact Detection	The effects of pacemaker artifact and electrical noise are minimized with artifact detection.

Battery (M5070A)

Type	9 Volt DC, 4.2 Ah, composed of disposable long-life lithium manganese dioxide primary cells.
Capacity	Minimum 200 shocks or 4 hours of operating time (EN 60601-2-4:2003)
Install-by Date	Battery is labeled with an install-by date of at least five years from date of manufacture.
Standby Life	Four years typical when battery is installed by the install-by date. (Will power the AED in standby state within the specified standby temperature range, assuming one battery insertion test and no defibrillation uses.)

SMART Pads

Adult SMART Pads Cartridge	M5071A defibrillation pads for patients 8 years of age and older or 55 lbs. (25 kg) and over.
Infant/Child SMART Pads Cartridge	M5072A defibrillation pads for patients under 8 years of age or 55 lbs. (25 kg). Rx only.
Energy Delivered	Adult: nominal 150 Joules into a 50 ohm load Infant/Child: nominal 50 Joules into a 50 ohm load
How Supplied	Disposable cartridge, containing adhesive defibrillation pads, clicks into defibrillator for an integrated pads solution.
Active Surface Area	13.2 in^2 (85 cm^2) each
Cable Length	Adult pads: 54 in (137.1 cm) Infant/Child pads: 40 in (101.6 cm)
Use-by Date	Cartridge is labeled with a use-by date of at least two years from date of manufacture.

Training Pads

Adult Training Pads Cartridge	M5073A
Infant/Child Training Pads Cartridge	M5074A
Function	Special pads put HeartStart OnSite into training mode and disable its energy delivery capability. Training pads feature 8 real-world training scripts. Used with training mat (included) or with adapters on manikins.

Automated and User-activated Self-tests

Daily Automatic Self-tests	Tests internal circuitry, waveform delivery system, pads cartridge and battery capacity.
Pads Integrity Test	Specifically tests readiness-for-use of pads (gel moisture).
Battery Insertion Test	Upon battery insertion, extensive automatic self-tests and user-interactive test check device readiness.
Status Indicator	Blinking green "Ready" light indicates ready for use. Audible "chirp" indicates need for maintenance.

Data Recording and Transmission

Infrared	Wireless transmission of event data to a PC or Palm® PDA, using the IrDA protocol.
Data Stored	First 15 minutes of ECG and the entire incident's events and analysis decisions.

* Refer to the HeartStart OnSite Defibrillator Owner's Manual for detailed product instructions.
All specifications based on 25° C unless otherwise noted. The defibrillator and its accessories are made of latex-free materials.

Philips—The trusted choice

- A Fortune Global 500 company, Philips is one of the world's largest medical products companies with annual revenue of over $7 billion.
- With over 350,000 automated external defibrillators installed, Philips is the leader in public access defibrillation.[11]
- Over 7 billion HeartStart Defibrillator service hours have been logged, with an additional 7 million added every day.
- Over 17% of Fortune 1000 companies, 8 out of 10 major airlines, and 43 professional sports teams rely on Philips HeartStart Defibrillators.

The HeartStart OnSite Defibrillator is the first defibrillator available for commercial and institutional users without a prescription. As the leader in innovative defibrillation technology, Philips is committed to making defibrillators more widely available so that more lives can be saved. Now with over-the-counter status, Philips is making it easier for companies and organizations to institute early defibrillation programs.

Defibrillators are one part of a well-planned resuscitation program, which also should include responder training in CPR and AED use. Philips recommends medical oversight of your early defibrillation program by a physician or other authorized medical practitioner. Consult your state and local requirements regarding owning and operating defibrillators, and medical oversight.

HeartStart user considerations

- You cannot use the HeartStart OnSite to treat yourself.
- Responding to cardiac arrest may require you to kneel.

To learn more about the HeartStart OnSite Defibrillator and Philips Medical Systems, visit www.philips.com/heartstart or call 1-800-453-6860.

References

[1] Andre, et al. Automated External Defibrillator Use by Untrained Bystanders: Can the Public-use Model Work? Prehospital Emergency Care 2004;8:284-291.

[2] Snyder, Time to Shock vs Voice Prompt Duration: Optimization of Defibrillators for Public Access and Home Deployment. 6th Scientific Congress of the European Resuscitation Council, Oct 2002.

[3] The Infant/Child pads cartridge is sold separately, and available only under the order of a physician.

[4] Yu et al. Adverse Outcomes of Interrupted Precordial Compression During Automated Defibrillation. Circulation 2002; 106:368-372.

[5] Eftesol T, Sunde K, Steen PA. Effects of Interrupting Precordial Compressions in the Calculated Probability of Defibrillation Success During Out-of-Hospital Cardiac Arrest. Circulation 2002; 105:2270-2273.

[6] Snyder et al. Biphasic Defibrillation Waveform Combined with AED-Imposed "Hands-Off" Intervals Significantly Affect Outcome Following Prolonged Cardiac Arrest. Abstract from 7th Scientific Congress of the European Council, 2004.

[7] Snyder & Morgan. CPR Interruption Interval Varies Widely Among Commercially Available AEDs. Abstract from 7th Scientific Congress of the European Council, 2004.

[8] Snyder, D.E. and Morgan, C. Wide Variations in Cardiopulonary Resuscitation Intervals Among Commercially Available Automated External Defibrillators May Affect Survival Despite High Defibrillation Efficacy. Critical Care Medicine. 2004;32(9) Supplement:S421-S424.

[9] Philips Medical Systems. SMART Biphasic Studies, listed alphabetically by study author.

[10] American Heart Association. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2005. 112:IV-36.

[11] Frost & Sullivan, 2005.

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Would you like to know more about our innovative products? Please do not hesitate to contact us. We would be glad to hear from you.

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